

APR 24 2012

5. 510(k) Summary

Device Trade Name: Apex Kirschner Wires and Steinmann Pins

Manufacturer: Apex Tools & Orthopedics Co.

Contact: Apex Tools & Orthopedics Co.
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Guangzhou, Guangdong,
CN-511356
CHINA
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Prepared by: Musculoskeletal Clinical Regulatory Advisers, LLC
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Washington, DC 20005
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Date Prepared: April 2, 2012

Classification: 21 CFR 888.3040

Class: II

Product Code: HTY and JDW

Reason for Special 510(k) Submission:

The purpose of this 510(k) is to provide the Apex Kirschner Wires and Steinmann Pins in "non-sterile" form as well as the previously cleared "sterile" form. There have been no changes to the intended use of the device or its fundamental scientific technology.

Indications For Use:

The Apex Kirschner Wires and Steinmann Pins are indicated for use in fixation of bone fractures, for bone reconstructions, as guide pins for insertion of other implants or implantation through the skin so that traction may be applied to the skeletal system.

Device Description:

Apex Kirschner Wires and Steinmann Pins are available in several diameters and lengths, in both threaded and non-threaded designs with a variety of point geometries.

Predicate Devices:

The modified Apex Kirschner Wires and Steinmann Pins are substantially equivalent to the predicate Apex Kirschner Wires and Steinmann Pins (K112254) with respect to indications, design, function, materials, and sterility assurance level.

Substantial Equivalence:

The Apex Kirschner Wires and Steinmann Pins are substantially equivalent to predicate devices with respect to indications, materials, and technological characteristics. To support the change from “sterile” to “non-sterile” Kirschner Wires and Steinmann Pins, a sterility validation study was performed to confirm that a sterility assurance level (SAL) of 10^{-6} was achieved with the recommended sterilization instructions.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Apex Tools & Orthopedics Company
% Musculoskeletal Clinical Regulatory Advisers, LLC
Ms. Hollace Saas Rhodes
1331 H Street, Northwest 12th Floor
Washington, District of Columbia 20005

APR 24 2012

Re: K121004

Trade/Device Name: Apex Kirschner Wires and Steinmann Pins
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY, JDW
Dated: April 2, 2012
Received: April 6, 2012

Dear Ms. Rhodes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

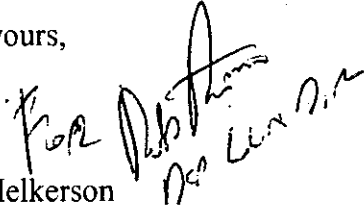
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over the typed name and title.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121004

4. Indications for Use

510(k) Number (if known): _____

Device Name: Apex Kirschner Wires and Steinmann Pins

The Apex Kirschner wires and Steinmann pins are indicated for use in fixation of bone fractures, for bone reconstructions, as guide pins for insertion of other implants or implantation through the skin so that traction may be applied to the skeletal system.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121004